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(74) Common Representative: RANBAXY LABORATORIES LIMITED; c/o DESHMUKH, Jay, R., 600 College Road East, Suite 2100, Princeton, NJ 08540 (US).

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(71) Applicant (for all designated States except US): RANBAXY LABORATORIES LIMITED [IN/IN]; 19, Nehru Place, New Delhi 110 019, Delhi (IN).

(72) Inventors; and

(75) Inventors/Applicants (for US only): KUMAR, Parveen [IN/IN]; 95, Sector 11, Panchkula, Haryana 134112 (IN). KATIAL, Vikas [IN/IN]; #1381, Sector - 29, Noida, Uttar Pradesh 201303 (IN). GIGRAS, Paresh [IN/IN]; c/o Shri Jagdish Chander Jitender Kumar, Chauraha Gali, Muradabad, Uttar Pradesh 244001 (IN). KUMAR, Sudeep [IN/IN]; B-107 Alaknanda Apt., Rampuri, Surya Nagar, Ghaziabad, Uttar Pradesh 201011 (IN). SHUKLA, Aniruddha [IN/IN]; #6148/5, Sector - D, Pocket - 6, Vasant Kunj, New Delhi 110070 (IN).

(54) Title: FERMENTATION PROCESS FOR THE PREPARATION OF PRAVASTATIN

(57) Abstract: The invention relates to a fermentation process for the preparation of substantially pure pravastatin. The process provides a method of producing pravastatin by microbial hydroxylation of compactin (ML-236B) by maintaining a concentration of compactin at not less than 300 µg /ml during the process. The process produces substantially pure pravastatin with reduced related impurities. The invention also relates to pharmaceutical compositions that include the substantially pure pravastatin.

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